"From Operative Morbidity to Risk Management"

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The article by Leonardi et al (see pag 395) considers the quantitative and qualitative aspects of adverse events and complications occurring during a consecutive series of therapeutic neuroradiology interventions: an investigation seldom carried out by a single centre. The authors should be commended for this work.It encourages a review of the shortcomings of our own systems. Many of the remarks below refer to current "surgical" techniques.

Operative Morbidity

Complication rates have today become mere information, a number among many, divorced from any human connection. They are perceived as inevitable and unchallengeable, consigned to the realm of fatality.

We know that the volume of interventions of any given practitioner, and indeed of any hospital, is inversely proportional to the morbidity/mortality encountered. However, an institution with a large case turnover only enjoys low morbidity rates if the surgeons working there are similarly exposed to large case numbers (Birkmeyer 2003). In other words, complications are linked to a particular environment and have particular causes. Complication rates are never absolute, but always relative and related to a given context.

The INR "risk" is established on the basis of the complications reported. Rather than trigger overall "risk management" strategies or quality control programmes, this approximation of the concept of risk has led to a *fait accompli* mindset (see Steiger 2001). As a result, meetings dedicated to complications discuss adverse events management but do not concern themselves with identifying and resolving possible structural or organisational causes at the root of complications.

Studies during the 80s had already shown that complications in INR were due to a lack, singly or combined, of knowledge, training or practice (Lasjaunias 1993). These shortcomings were, and still are, specific to our particular practice and as such demand specific solutions in terms of both quality and adverse events analysis (Lasjaunias 2001, Vincent 2003).

Morbidity and the Unexpected

A predictable, avoidable complication is untolerable.

Complications that are the result of insufficient *practice* or *skilling* argue in favour of concentrating activity in a facility that already handles a large number of patients. A policy of spreading human and material resources does not foster low morbidity and mortality – although decentralisation must of course take place once the main facility is saturated. This is

a rule that applies to both rare and frequent pathologies since the whole concept of critical mass is somewhat more complex than the mere sum of the operations or therapies administered.

Training in INR is the cause of great concern all the more so since no official training in neuroradiology (NR) and especially interventional NR (INR) exists. Only recently have university diplomas appeared in the field of neurovascular diseases. This lack of *training* is one of the reasons for the lack of standardisation of methods, protocols and procedures (Lasjaunias 2001). As already witnessed in other specialties, the risk is that all patients will be lumped together in cohort or trial, creating a "system out of uncertainty or ignorance" and providing a formidable alibi that dispenses knowledge by only asking questions: it is the eternal debate between Socrates and Aristotle.

Being forewarned about the future often means having observed the facts in the past. Yet we know that the recommendations endorsed and published are only followed by an average of 54.9% of prescribers (54.9% in preventive care; 53.9% in acute care and 56.1% in chronic care (Mc Glynn 2003)).

Moreover the foreseeable is not just what has already happened and been experience. Some complications may be due to an unforeseeable, unknown event, illustrating the challenge we face as doctors (Lasjaunias 2000). Here we are on ethical ground.

- an unknown "clinical" event belongs to those situations in which the unforeseeable and unknown takes place. It demonstrates how, despite the statistics, the individual patient continues to be unique. The prudent practitioner must draw the line of the "known", i.e. of his own knowledge or ability to anticipate a clinical event. It will be a line that varies from one specialist to another. No treatment is sometimes the most advisable – and best – decision. Caution does not equate with failure to act.
- "Operative" unknowns have to do with using tools, approaches or emboli whose effects are either unknown or unmastered. This kind of adverse event accounts for much of today's operative morbidity. The enthusiastic hard sell of a series of what subsequently proved short-lived techniques are a lesson to all.

Importantly, what may be considered a tolerable **complication** rate when treating an overt "clinical disease" requiring a result within a given time lapse will not apply in the case of an "image-disease", i.e. an incidental discovery. Patient's expectations are different in these two situations, as is the whole concept of operative morbidity. The conditions (**risks**) under which the decision is taken to perform the intervention will be grounded on different justifications in the two cases. And this will condition the type of information given to patients and their relatives.

Standards

Today, interventional neuroradiology has created its own sector of activity (and market), thereby implicitly creating treatment hopes and expectations in the light of the favourable clinical outcome. Some published results, and especially most unpublished data, show that results vary from centre to centre, however.

Today complications are variously categorised as a function of treatment technique or site. The selection of device has replaced the selection of patients likely to benefit from the treatment proposed. As a result, we compare treatment techniques and not treatment indications. By the same token the "goal of treatment" has become the image target of the disease rather than a clinical objective. Treatment has become a technological mechanics and perceived as such by the general public. Doubt and a form of vigilance have been set aside in favour of the certainties afforded by grouping all events under one umbrella in a context where the human factor carries less weight.

The plethora of devices available cannot, however, hide the lack of any real conceptual breakthroughs. We are currently in a phase of muted innovation, as the abundance of "Me-Too products" demonstrate (Lee 2004).

Narrowing decisions to treat to the simple choice of what material to use has rendered many interventional neuroradiologists overly dependent on the imaged result, overly concerned with just the technical issues and the events that punctuate their practice. We are at a stage when the tool is treating the image and the main issue at stake is their reciprocal reliability. Technical dexterity becomes the only human requirement necessary, imaging technology our only security while complications are an accident whose solution (and causes lies in technology.

Treatment failures rightly calling for explanations have generated technical research rather than investigation of our facilities and theoretical training methods. Decision-making excellence is measured by its effects, not by its processes. The "near misses" of civil aviation pilots simply do not exist in INR. It is only the bottom line that counts, as our simplistic clinical "scoring system" shows. We have not yet taken on board the mindset of safety and reliability as something to be achieved before the event.

There is an important difference between operative safety – which translates as quality and risk management – and objective lack of safety that is adverse outcome analysis (Vincent 2003): the former devises strategies and provides preventive measures, the latter provides remedies and is retrospective.

Finally, what **information is given to the patient** on the subject of morbidity and mortality? What do the statistics we provide actually express when they have been assessed by a team? Do they include the shortcomings of our own training or practice, or just the unforeseeable accidents? What does the patient learn about better performance in other facilities?

If we really want to prevent complications we must seriously consider the following:

- clinical training in interventional neuroradiology;
- creating real critical mass references;
- compulsory follow-up by yhe operators;
- the stability of techniques used;
- how treatment innovation is introduced;
- professional auditing of practice and results.

Both our imaging techniques and quantified morbidity figures sideline the whole issue of doctor/patient relations. They also sideline the social dimension of complications and their sometimes unjust or unacceptable nature, as the increase in litigation in INR shows.

In short, at this stage of its development and public acknowledgement, interventional neuroradiology must develop a professional strategy, reflect on its workings and begin systematic assessment of its practices and results.

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